

REMARKS

Pending claims 1-17, 23-25, 27-43, 45-47, 49-54, 61-73, 77-86, 103, 105-111, 127, 129-132, 134-136, 138-144, 146-157, 159-164, as amended, are under consideration. The amended claims are directed to an elected invention of Group I. Claims 1-47, 49-54, 61-73, 77-86, 103-11, and 127-164 stand rejected for being indefinite under 35 U.S.C. § 112, first and second paragraphs with respect to the term "prodrugs". Claims 1-47, 49-54, 61-73, 77-86, 103-11, and 127-164 also are subject to a provisional obviousness-type double patenting rejection. Applicants respectfully traverse the rejections.

Claims 1, 43, 103, 127, 132, 136, and 144 recite the term "prodrugs", which the Examiner deems indefinite in accordance with 35 U.S.C. § 112, second paragraph. Applications respectfully submit that the term "prodrugs" refer to compounds that undergo *in vivo* hydrolysis to provide active parent compounds within the scope of the claimed invention. Where compounds contain groups that can be hydrolyzed, for example esters, carbamates, and amides, the claimed compound can be hydrolyzed to provide an active parent compound.

Claims 153-164 have been rejected under 35 U.S.C. 112, first paragraph. Claim 157 has been amended to recite the specific indications for the claimed methods. Claim 158 has been cancelled. The Examiner contends that the applicants' claimed methods of treatment are related to use of histamine-3 receptor modulators, which are speculative in nature. Applicants respectfully disagree.

It is well-recognized in the cases cited by the Examiner that to satisfy the statutory requirements for establishing and enabling utility, the applicants should provide a reasonable correlation between using the claimed compounds and their intended utility. In the present case applicants show that the claimed compounds are useful for treating and/or preventing indications associated with histamine-3 modulation. Some specific indications, as recited in the claims, are gastrointestinal disorders, obesity, sleep disorders, asthma, Alzheimer's disease, bipolar disorder, cognitive disorders, for example schizophrenia, septic shock, and other uses specifically delineated in amended claim 157.

Applicants respectfully submit that all methods claimed in Claim 157 are well-established in the scientific literature and are clearly and particularly detailed in the present

application. Applicants describe specific methods for determining biological activity of the claimed compounds. A measure of receptor binding is reported for compounds throughout the scope of the claimed genus. (See, specification, pages 63-69.) The effect of treatment of diseases and conditions via histamine-3 receptor modulation is well-documented in the literature. Applicants have clearly and specifically named reported references describing claimed uses in the specification on pages 189-193. Such references reflect the current understanding of those with skill in the art. The references are presently made of record in an accompanying Supplemental IDS and Form PTO-1449. Applicants further describe suitable dosage forms and suitable amounts in the specification on at least page 193, line 2, through page 194, line 14. Such showing is more than sufficient to support a credible showing of the asserted uses.

Moreover, even in light of some doubt as to the claimed utility, Applicants are not required prove such utility to a scientific certainty. Two abstracts cited by the Examiner reciting tentative language such as "preliminary findings" and "intriguing possibility" do not undermine an entire body of well-established, cited literature provided by the applicants. The study of histamine-3 receptor modulation clearly is more than a mere guess with respect to the claimed utilities. To require the applicants to provide more evidence than is presently provided requires the applicants to repeat information that is readily available to one with skill in the art without undue experimentation and unjustly limits the applicants to claiming only what has been proven to certainty and not what the applicants conceive and reasonably support.

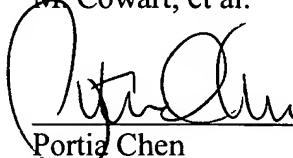
Applicants further submit that the provisional obviousness-type double patenting rejection of claims 1-47, 49-54, 61-73, 77-86, 103-111, and 127-164 in view of claims 1-71 of U.S. Patent Application Serial No. 10/044,495 has been rendered moot. U.S. Patent Application Serial No. 10/044,495 is no longer pending.

As such, the applicants respectfully submit the application is in a condition for allowance and respectfully request notification thereof. The amended claims are attached in accordance with the Revised Guidelines for submitting amendments under 37 C.F.R. § 1.121. Applicants reserve the right to file divisional applications on any non-pending or non-elected subject matter in the application.

Should the Examiner have any questions or concerns regarding the foregoing, he is respectfully invited to contact the undersigned by telephone at the phone number provided below.

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Respectfully submitted,
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